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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,201	11/30/2001	Shoujun Chen	13321-007001	8537

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EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/010,201	Applicant(s) CHEN ET AL	
Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-35 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt (US 4248861) or Rosenbaum (US 5585386) in view of Watkins et al. (US 6159473), or vice versa, Watkins in view of Schutt or Rosenbaum.

Schutt teaches a skin composition comprising Kava Kava and a carrier (Col. 3, lines 33-41, 48-68; Col. 4, lines 1-5; Col. 5, Examples 3 and 4). This composition is applied to the skin to treat burns and can be prepared in any desired manner and in any suitable order or sequence of addition of the various components (Col. 4, lines 31-44). The Kava Kava is present in amounts from 0.5 to 3 parts by weight (Col. 3, lines 33-41). It is the position of the Examiner that Kava Kava contains all the kavalactones claimed

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in the instant application. Schutt does not expressly teach that the Kava Kava extracts are used to treat pain.

Rosenbaum teaches a topical composition comprising kavain, dihydrokavain, methysticin, dihydromethysticin and a physiologically acceptable carrier (Col. 3, lines 17-67; Col. 4, lines 1-26). The composition is in the form of a ointment or lotion (Col. 4, lines 12-22; Col. 5 & 6, Examples 1, 3 and 4). The kavalactones are present in the invention from approximately 0.05% to 10% by weight (Col. 3, lines 19-23).

Rosenbaum does not expressly teach that the kavalactones are used to treat pain.

Watkins teaches that Kava Kava is a known topical analgesic (Col. 1, lines 25-45; Col. 2, lines 4-6 and Table 1).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

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Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare an ointment comprising Kava Kava extracts, which encompass kavalactones, to treat pain.

One of ordinary skill in the art would have been motivated to do this to deliver a pain treatment topically to a localized area of pain.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

When the references are used in the reverse order (Watkins in view of Schutt or Rosenbaum), a *prima facie* case of obvious is also established. Watkins teaches that Kava Kava extracts have a pain relieving effect when applied as a topical analgesic. While Watkins teaches a throat spray as the formulation, the references generally teaches that Kava Kava extracts are a topical analgesic. To treat other locations on a host or patient it would be obvious to use other vehicles to deliver the analgesic, such as an ointment applied to the skin. Schutt and Rosenbaum both teach topical ointments that contain Kava Kava or kavalactones.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare an treat pain with kavalactones topically in the form of an ointment.

One of ordinary skill in the art would have been motivated to do this to deliver pain relief to various parts of a patient in the most effective manner.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmussen et al. (US 6379696) in view of Elbakyan (WO 00/30578) further in view of Schwabe (US 5296224). Asmussen teaches a transdermal therapeutic system comprising kawain (Col 3- 4, Claim 1).

Asmussen does not expressly teach the patch composition and components of the composition. Asmussen further does not expressly teach that the kawain is used to treat pain

Elbakyan teaches a transdermal patch composition comprising an active agent in a polymer matrix (Page 6, lines 10-27), an absorbent layer wherein the active composition is supported and a nonabsorbent backing layer (Page 8, lines 13-30).

Elbakyan does not expressly teach a kavalactone as the active agent.

Schwabe teaches that kawain is a kavalactone. Schwabe further teaches other suitable kavalactones such as dihydrokawain, methysticin, dihydromethysticin and yangonin (Col. 1, lines 14-53). Schwabe does not expressly teach that the kavalactones treat pain.

Watkins teaches that Kava Kava is a known topical analgesic (Col. 1, lines 25-45; Col. 2, lines 4-6 and Table 1).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal therapeutic system in the form of a transdermal patch comprising kavalactones for treating pain. Asmussen teaches

kawain in a transdermal system. Elbakyan teaches the transdermal system can be in the form of a patch. Schwabe teaches the other suitable kavalactones. Watkins teaches the kavalactones can be used to treat pain.

One of ordinary skill in the art would have been motivated to do this to provide a slow-release therapeutic composition for topical administration in the treatment of skin conditions, whether it is burns or hypertrophic skin accumulations or pain.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600